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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2014-0012]

Information for Providers to Share with Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, Sexually Transmitted Infections, and other Health Outcomes

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), announces the availability of "Information for Providers to Share with Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, Sexually Transmitted Infections, and other Health Outcomes."

FOR FURTHER INFORMATION CONTACT: Division of HIV/AIDS, National Centers for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS D-21, Atlanta, Georgia 30329; phone: 404-639-5200; email: circumcision@cdc.gov.

SUPPLEMENTARY INFORMATION: On December 2, 2014, CDC published a notice in the *Federal Register* (79 FR 71433) requesting public comment on a draft document titled *Recommendations for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV Infection, STIs, and Other Health Outcomes* (referred to as The Initial Draft Document). On August 30, 2018, the title was changed to *Information for Providers to Share with Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, Sexually Transmitted Infections, and other Health Outcomes* to better align with the content in the final version of the document.

The intent of this document is to assist health care providers in the United States who share information with men and parents of male infants, children and adolescents for their use in decision making about male circumcision as it relates to the prevention of human immunodeficiency virus (HIV) infection, sexually transmitted infections (STIs), and other health outcomes. Such decision making is made in the context of not only health considerations, but also other social, cultural, ethical, and religious factors. Although observational and ecologic data have been accumulating about infant male circumcision for many years, clinical trials conducted between 2005–2010 have

demonstrated safety and significant efficacy of voluntary adult male circumcision performed by clinicians for reducing the risk of acquisition of human immunodeficiency virus (HIV) by a male during penile-vaginal sex ('heterosexual sex'). Three randomized clinical trials conducted in Kenya, Uganda, and South Africa^{1,2,3} showed that adult male circumcision reduced HIV infection risk by 50-60%. These trials also found that adult circumcision reduced the risk of men acquiring two common sexually transmitted infections (STIs), herpes simplex virus type-2 (HSV-2) and types of human papilloma virus (HPV) that can cause penile and other anogenital cancers. Since the release of these trial data, various medical professional organizations have updated their information about adult male and infant male circumcision.

Initial comment period. The initial comment period was open for public and peer review during December 2, 2014 - January 16, 2015.

Public comments (initial comment period). CDC received 3,234 comments on the *Initial Draft Document* from the

¹ Bailey RC, Moses S, Parker CB, et al. Male circumcision for HIV prevention in young men in Kisumu, Kenya: a randomised controlled trial. *Lancet*. 2007;369(9562):643-656.

² Auvert B, Taljaard D, Lagarde E, Sobngwi-Tambekou J, Sitta R, Puren A. Randomized, controlled intervention trial of male circumcision for reduction of HIV infection risk: the ANRS 1265 Trial. *PLoS Med*. 2005;2(11):e298.

³ Gray RH, Kigozi G, Serwadda D, et al. Male circumcision for HIV prevention in men in Rakai, Uganda: a randomised trial. *Lancet*. 2007;369(9562):657-666.

public, including but not limited to individuals (e.g. parents and physicians) and representatives of professional medical and community-based organizations. A summary of public comments and responses to comments, including changes are noted in the *Summary of Public Comments and CDC Responses to Public Comments for Information for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, Sexually Transmitted Infections, and other Health Outcomes*. This document is in the docket at: www.regulations.gov and at <https://www.cdc.gov/hiv/pdf/risk/MC-HISA-Public-Comments-and-Responses.pdf>.

Peer Review comments (initial comment period). Peer reviewers were asked to review the *Initial Draft Document* and its companion document, *Background, Methods, and Synthesis of Scientific Information Used to Inform the 'Recommendations for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, STIs, and other Health Outcomes.'* On August 30, 2018, the title of this companion document was changed to *Background, Methods, and Synthesis of Scientific Information Used to Inform 'Information for Providers to Share with Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV Infection, Sexually*

Transmitted Infections, and other Health Outcomes' to better align with the content in the final document. CDC considers these documents to be highly influential scientific assessments (HISA) as defined by the Office of Management and Budget's (OMB) directive, *Final Information Quality Bulletin for Peer Review*, dated December 15, 2004. HISA documents are subject to peer review.

Peer reviewers evaluated the appropriateness of the methods and of the interpretation of findings, including generalizability of the evidence to the United States. Peer review comments were received from three physician peer reviewers. A copy of peer review comments, CDC responses, and changes are noted in the documents titled: *Peer Review Comments and CDC Responses for Peer Review Comments and CDC Responses for "Information for Providers to Share with Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, Sexually Transmitted Infections, and other Health Outcomes"* and *"Background, Methods, and Synthesis of Scientific Information Used to Inform 'Information for Providers to Share with Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV Infection, Sexually Transmitted Infections, and other Health Outcomes.'* These documents are in the public docket at www.regulations.gov

and at <https://www.cdc.gov/hiv/pdf/risk/MC-HISA-Round-1-Peer-Review-Comments-and-Responses.pdf>.

Second comment period. The second comment period was opened during September 15 - 30, 2016, for peer review only.

Peer Review comments (second comment period). Peer Reviewers reviewed and commented on a revised copy of the *Initial Draft Document*. Peer Reviewers were asked to limit their comments only to changes that were made as a result of the initial comment period.

Comments were received from two peer reviewers. A summary of peer review comments, CDC responses, and changes made are noted in the *Summary of Peer Review Comments and CDC Responses to Second Round of Peer Review Comments for Information for Providers to Share with Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV Infection, Sexually Transmitted Infections, and other Health Outcomes* are in the public docket at www.regulations.gov and at <https://www.cdc.gov/hiv/pdf/risk/MC-HISA-Round-2-Peer-Review-Comments-and-Responses.pdf>.

All comments were carefully reviewed and considered in the development of the final version of the document found

in the public docket at www.regulations.gov and at
<https://www.cdc.gov/hiv/risk/male-circumcision.html>.

Dated: February 14, 2019.

Sandra Cashman,

Executive Secretary,

Centers for Disease Control and Prevention.

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